REMARKS

Claims 3 and 16 are pending in the instant application. Claims 3 and 16 have been amended and new claims 17 through 21 have been added. Support for these amendments is provided in the specification at page 3, lines 19-21, page 15, lines 32-33 and Table 7 at page 86. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

Rejection under 35 U.S.C. §112, first paragraph - Lack of Enablement

Claims 3 and 16 have been rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner has acknowledged the specification to be enabling for a method of diagnosing the presence of breast cancer in a patient comprising determining levels of a breast specific polynucleotide designated as SEQ ID NO:4 in cells tissue or bodily fluids in a patient and comparing the determined levels of a polynucleotide comprising SEQ ID NO:4, wherein a change in determined levels of a polynucleotide of SEQ ID NO:4 in said patient versus normal human control is associate with presence of breast cancer. However,

the Examiner suggests that the specification does not reasonably provide enablement for a polynucleotide encoding a polypeptide encoded by SEQ ID NO:4 for the presence of any cancer.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to be drawn to detecting the presence of those cancer types disclosed in Table 7 at page 86 of the specification to have expression levels similar to, if not greater than, expression levels in breast cancer. The Examiner has acknowledged this evidence to establish that SEQ ID NO:4 is a unique or molecular marker for breast cancer. Clearly, evidence of expression levels in cancer tissue samples from the colon, endometrium, kidney, liver, lung, ovary, prostate, small intestine, stomach, testis and uterus similar to, if not greater than those set forth for breast cancer samples, must be accepted as enabling for these types of cancer as well.

The Examiner also suggests that Applicants' specification does not evidence the intended use of degenerate sequences of SEQ ID NO:4, which is embraced by the claim language. The Examiner suggests that while the record has clearly established that SEQ ID NO:4 is a unique or molecular marker for breast cancer, there is insufficient evidence provided to support the use of degenerate sequences in a diagnostic method for any cancer and specifically

cancer.

Accordingly, while not conceding to the Examiner's position, in an earnest effort to advance the prosecution of this case, Applicants' have amended the claims to specify that by other polynucleotides encoding SEQ ID NO:4, it is only meant to include naturally occurring allelic variants encoding a polypeptide encoded by SEQ ID NO:4. Support for this amendment is provided in the specification at page 15, lines 32-33. Applicants have also amended the claims in accordance with teachings at page 3 to state that native mRNA encoded by a gene comprising SEQ ID NO:4 can also be determined.

The presence of naturally occurring allelic variants with similar biological activities is well-established in humans. Thus, it is reasonable to expect that naturally occurring allelic variants of SEQ ID NO:4 exist and that like SEQ ID NO:4 such naturally occurring allelic variants can be used to detect the presence of cancer of the breast, colon, endometrium, kidney, liver, lung, ovary, prostate, small intestine, stomach, testis or uterus. Accordingly, the evidence of record, acknowledged by the Examiner to establish SEQ ID NO:4 as a unique or molecular marker for breast cancer, and that presented in Table 7 relating to SEQ ID NO:4 being a molecular marker in cancer of the colon, endometrium,

kidney, liver, lung, ovary, prostate, small intestine, stomach, testis and uterus, is indicative to the skilled artisan of naturally occurring allelic variants of SEQ ID NO:4 also being unique or molecular markers for these cancers.

Thus, the claims as amended meet the enablement requirements of 35 U.S.C. 112, first paragraph. Withdrawal of these rejections is therefore respectfully requested.

Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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